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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,779	06/28/2007	Thienna Ho	70063.00004	4440
58688 7590 01/21/2009 CONNOLLY BOVE LODGE & HUTZ LLP P.O. BOX 2207 WILMINGTON, DE 19899			EXAMINER YU, GINA C	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 01/21/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/599,779

**Applicant(s)**

HO, THIENNA

**Examiner**

GINA C. YU

**Art Unit**

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-20 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of amendment filed on October 8, 2008. All claim rejections made in the previous Office action dated July 8, 2008 are withdrawn in view of the claim amendment made by applicants. New rejections are made.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 4, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 4 recites a method of "further comprising delivering the effective amount of methyl sulfonyl methane by periodically ingesting a compound comprising methyl sulfonyl methane". Claim 4 depends on claim 1, which already requires orally administering an effective amount of methyl sulfonyl methane to lighten skin tone. Does claim 4 require a double dosage of the oral composition, and if so, what is the true "effective amount" of the invention?

Claim 5 is rejected as the claim depends on the indefinite base claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 4, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Herschler (US 44863748).**

Herschler discloses a clinical experiment which consists of orally administering methyl sulfonyl methane in amounts ranging from 250 to 500 mg daily in solution for seven months to over one year. See Example 12. Since the prior art teaches the same compound, the recited skin-lightening property of the MSM is necessarily present in the prior art. Thus the oral administration of MSM as practiced by Example 12 inherently carries out the method of the presently claimed process of using MSM.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 3, 5-7, 9-12, 17, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler (US 4296130) as applied to claims 1, 2, 4, 18, 19 as above, and further in view of Petrus (US 6573299 B1).**

Herschler is relied upon as discussed above. The reference further discloses that MSM is administered in various routes, including topical and oral methods. The reference also teaches in col. 2, lines 18 – 68 that MSM is a naturally occurring substance, and beautifies the complexion of the skin when applied topically. The reference teaches that the composition can be in solution, cream, lotion or gel for topical administration or oral administration, depending on its intended use. See col. 2, lines

41 – 46. Since the reference teaches that MSM improves the complexion of the skin, one of ordinary skill in the art would obviously have observed and/or expected that MSM changes skin color tone after the MSM treatment.

Herschler also teaches 15% MSM composition and further teaches that greater amount of MSM could be used if the composition is heated and mixed prior to topical application. See col. 5, lines 34- 38; instant claims 9-11. Since the reference teaches the efficacy of MSM in beautifying skin, finding an optimal daily oral dosage of MSM would have been obvious to one of ordinary skill in the art.

Petrus teaches method and compositions for treatment of the aging eye and the aging skin around the eyes. See col. 2, lines 28 – 34. The reference teaches that it is well known in pharmaceutical art that MSM “penetrates deep within the skin's surface to moisturize, soften and rejuvenate dry, aging, or damaged skin”. See col. 11, lines 60-64. The therapeutic dosage range for MSM is 2-10 grams and 1-5 grams per day, orally and topically, respectively. Table 1 of the reference also teaches other orally administrable bio-affecting agents including proteins, vitamins, minerals, and antioxidants. Thus combining these agents with MSM to either oral or topical formulations would have been obvious to one of ordinary skill in the art. See instant claim 5.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Herschler by administering about 2-10 mg of MSM (28.6-142.9 mg/Kg, with body weight of 70 Kg) as motivated by Petrus, because both references teach using MSM orally and/or topically to beautify and rejuvenate the skin. Since Herschler suggests

that administration of MSM changes skin tone and oral administration of the component, and Petrus teaches of safe and effective dosage of MSM for cosmetic purposes, one of ordinary skill in the art would have had a reasonable expectation of successfully improving skin tone by combining the teachings of the references.

**Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler and Petrus as applied to claims 1-7, 9-12, 17-20 as above, and further in view of Kirby et al. (US 6444234 B1).**

While Herschler teaches making topical formulations comprising MSM, the reference fails to teach transdermal patch.

Kirby discloses a transdermal delivery system of pharmaceutical agents including MSM. See Tables and Examples.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the method of the combined references by formulating a transdermal patch as motivated by Kirby because the latter teaches a rapid and non-irritating transdermal delivery of pharmaceutically active agents. The skilled artisan would have had a reasonable expectation of successfully administering MSM in a rapid and safe route.

**Claims 13-16 are as being unpatentable over Herschler and Petrus as applied to claims 1-7, 9-12, 17-20 as above, and further in view of Flick (Cosmetic and Toiletry Formulations, vol. 6).**

While Herschler teaches that administering MSM to a subject softens the skin and beautify the complexion, the reference fails to teach adding an exfoliate.

Flick teaches glycolic acid skin rejuvenating cream.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the Herschler method of administering MSM by incorporating to the topical composition an exfoliate such as glycolic acid as motivated by Flick because both references teach skin treatment compositions which beautify the skin and Flick specifically teaches rejuvenating function of glycolic acid.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/  
Primary Patent Examiner, Art Unit 1611